

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Equivalent of Form PTO/SB/08A (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

<div style="text-align: center;"> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p><i>(Use as many sheets as necessary)</i></p> </div>				Complete if Known	
				Application Number	10/564,744
				§ 371 Date	March 3, 2006
				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	Gupta, Anish
Sheet	1	of	1	Attorney Docket Number	0609.5160001/TJS/PAC/JJY

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

652722v1

Examiner Signature	/Anish Gupta/	Date Considered	02/01/2009
-----------------------	---------------	--------------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/564,744
				§ 371 Date	March 3, 2006
				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	Gupta, Anish
Sheet	1	of	4	Attorney Docket Number	0609.5160001/TJS/PAC/JJY

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
/AG/	NPL1	Barden, J.A. and Kemp, B.E., "NMR Solution Structure of Human Parathyroid Hormone(1-34)," <i>Biochemistry</i> 32:7126-7132, American Chemical Society (1993)	
/AG/	NPL2	Behar, V., <i>et al.</i> , "Photoaffinity Cross-linking Identifies Differences in the Interactions of an Agonist and an Antagonist with the Parathyroid Hormone/Parathyroid Hormone-related Protein Receptor," <i>J. Biol. Chem.</i> 275:9-17, American Society for Biochemistry and Molecular Biology, Inc. (2000)	
/AG/	NPL3	Bergwitz, C., <i>et al.</i> , "Full Activation of Chimeric Receptors by Hybrids between Parathyroid Hormone and Calcitonin," <i>J. Biol. Chem.</i> 271:26469-26472, The American Society for Biochemistry and Molecular Biology, Inc. (1996)	
/AG/	NPL4	Berridge, M.J., <i>et al.</i> , "Changes in the levels of inositol phosphates after agonist-dependent hydrolysis of membrane phosphoinositides," <i>Biochem. J.</i> 212:473-482, The Biochemical Society (1983)	
/AG/	NPL5	Bisello, A., <i>et al.</i> , "Parathyroid Hormone-Receptor Interactions Identified Directly by Photocross-linking and Molecular Modeling Studies," <i>J. Biol. Chem.</i> 273:22498-22505, The American Society for Biochemistry and Molecular Biology, Inc. (1998)	
/AG/	NPL6	Carter, P.H and Gardella, T.J., "Zinc(II)-mediated enhancement of the agonist activity of histidine-substituted parathyroid hormone(1-14) analogues," <i>Biochem. Biophys. Acta</i> 1538:290-304, Elsevier Science B.V. (2001)	
/AG/	NPL7	Chen, Z., <i>et al.</i> , "Structure of the Osteogenic 1-31 Fragment of Human Parathyroid Hormone," <i>Biochemistry</i> 39:12766-12777, American Chemical Society (2000)	
/AG/	NPL8	Condon, S.M., <i>et al.</i> , "The Bioactive Conformation of Human Parathyroid Hormone. Structural Evidence for the Extended Helix Postulate," <i>J. Am. Chem. Soc.</i> 122:3007-3014, American Chemical Society (2000)	
/AG/	NPL9	Creighton, T.E., ed., "3.2. Evolutionary Divergence of Proteins," in: <i>Proteins: Structures and Molecular Properties</i> , 2 nd Ed., W.H. Freeman and Co., New York, NY, pp 108-114 (1993)	
/AG/	NPL10	Dempster, D.W., <i>et al.</i> , "Anabolic Actions of Parathyroid Hormone on Bone," <i>Endocrine Rev.</i> 14:690-709, The Endocrine Society (1993)	

665208v1

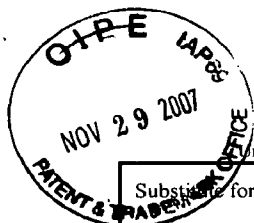
NON PATENT LITERATURE DOCUMENTS

Examiner Signature	/Anish Gupta/	Date Considered	02/01/2009
--------------------	---------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
Application Number				10/564,744	
§ 371 Date				March 3, 2006	
First Named Inventor				GARDELLA, Thomas J.	
Art Unit				1654	
Examiner Name				Gupta, Anish	
Attorney Docket Number				0609.5160001/TJS/PAC/JJY	
Sheet	2	of	4		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published			T ²
/AG/	NPL11	Dempster, D.W., <i>et al.</i> , "Erratum: Anabolic Actions of Parathyroid Hormone on Bone," <i>Endocrine Rev.</i> 15:261, The Endocrine Society (1994)			
/AG/	NPL12	Dempster, <i>et al.</i> , "On the Mechanism of Cancellous Bone Preservation in Postmenopausal Women with Mild Primary Hyperparathyroidism," <i>J. Clinical Endocrinology & Metabolism</i> 84:1562-1566, The Endocrine Society (1999)			
/AG/	NPL13	Fairwell, T., <i>et al.</i> , "Total Solid-Phase Synthesis, Purification, and Characterization of Human Parathyroid Hormone-(1-84)," <i>Biochemistry</i> 22:2691-2697, American Chemical Society (1983)			
/AG/	NPL14	Gardella, T.J., <i>et al.</i> , "Analysis of Parathyroid Hormone's Principal Receptor Binding Region by Site-Directed Mutagenesis and Analog Design," <i>Endocrinol.</i> 132:2024-2030, Endocrine Society (1993)			
/AG/	NPL15	Gronwald, W., <i>et al.</i> , "Structure of Recombinant Human Parathyroid Hormone in Solution Using Multidimensional NMR Spectroscopy," <i>Chem. Hoppe-Seyler</i> 377:175-186, Walter de Gruyter & Co. (1996)			
/AG/	NPL16	Goud, N.A., <i>et al.</i> , "Solid-Phase Synthesis and Biologic Activity of Human Parathyroid Hormone(1-84)," <i>J. Bone Min. Res.</i> 6:781-789, Mary Ann Liebert, Inc. (1991)			
/AG/	NPL17	Hoare, S.R.J., <i>et al.</i> , "Evaluating the Signal Transduction Mechanism of the Parathyroid Hormone 1 Receptor," <i>J. Biol. Chem.</i> 276:7741-7753, American Society for Biochemistry and Molecular Biology (2001)			
/AG/	NPL18	Jin, L., <i>et al.</i> , "Crystal Structure of Human Parathyroid Hormone 1-34 at 0.9-Å Resolution," <i>J. Biol. Chem.</i> 275:27238-27244, The American Society for Biochemistry and Molecular Biology, Inc. (2000)			
/AG/	NPL19	Jüppner, H., <i>et al.</i> , "A G Protein-Linked Receptor for Parathyroid Hormone and Parathyroid Hormone-Related Peptide," <i>Science</i> 254:1024-1026, American Society for the Advancement of Science (1991)			
NON PATENT LITERATURE DOCUMENTS					

Examiner Signature	/Anish Gupta/	Date Considered	02/01/2009
--------------------	---------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
Sheet 3 of 4				Application Number	10/564,744
				§ 371 Date	March 3, 2006
				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	Gupta, Anish
				Attorney Docket Number	0609.5160001/TJS/PAC/JJY
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published			T ²
/AG/	NPL20	Kronenberg, H.M., <i>et al.</i> , "Parathyroid Hormone: Biosynthesis, Secretion, Chemistry, and Action" in: <i>Handbook of Experimental Pharmacology</i> , Mundy, G.R., and Martin, T.J., eds., Springer-Verlag, Berlin, Germany, pp. 507-567 (1993)			
/AG/	NPL21	Luck, M.D., <i>et al.</i> , "The (1-14) Fragment of Parathyroid Hormone (PTH) Activates Intact and Amino-Terminally Truncated PTH-1 Receptors," <i>Mol. Endocrinol.</i> 13:670-680, The Endocrine Society (1999)			
/AG/	NPL22	Marx, U.C., <i>et al.</i> , "Structure of Human Parathyroid Hormone 1-37 in Solution," <i>J. Biol. Chem.</i> 270:15194-15202, The American Society for Biochemistry and Molecular Biology, Inc. (1995)			
/AG/	NPL23	Marx, U.C., <i>et al.</i> , "Structure Activity Relation of NH ₂ -Terminal Human Parathyroid Hormone Fragments," <i>J. Biol. Chem.</i> 273:4308-4316, American Society for Biochemistry and Molecular Biology, Inc. (1998)			
/AG/	NPL24	Marx, U.C., <i>et al.</i> , "Solution Structure of Human Parathyroid Hormone Fragments hPTH(1-34) and hPTH (1-39) and Bovine Parathyroid Hormone Fragment bPTH(1-37)," <i>Biochem. Biophys. Res. Commun.</i> 267:213-220, Academic Press (2000)			
/AG/	NPL25	Neer, R.M., <i>et al.</i> , "Effect of Parathyroid Hormone (1-34) on Fractures and Bone Mineral Density in Postmenopausal Women with Osteoporosis," <i>N. Eng. J. Med.</i> 344:1434-1441, Massachusetts Medical Society (2001)			
/AG/	NPL26	Pellegrini, M., <i>et al.</i> , "Binding Domain of Human Parathyroid Hormone Receptor: From Conformation to Function," <i>Biochemistry</i> 37:12737-12743, American Chemical Society (1998)			
/AG/	NPL27	Robinson J.R. ed., "Methods to Achieve Controlled Drug Delivery," in: <i>Sustained and Controlled Release Drug Delivery Systems</i> , Marcel Dekker, New York, NY, pp 557-593 (1978)			
/AG/	NPL28	Rölz, C. and Mierke, D.F., "Characterization of the molecular motions of constitutively active G protein-coupled receptors for parathyroid hormone," <i>Biophys. Chem.</i> 89:119-128, Elsevier Science B.V. (2001)			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published			T ²

Examiner Signature	/Anish Gupta/	Date Considered	02/01/2009
--------------------	---------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/564,744
				§ 371 Date	March 3, 2006
				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	Gupta, Anish
Sheet	4	of	4	Attorney Docket Number	0609.5160001/TJS/PAC/JJY
/AG/	NPL29	Shimizu, M., <i>et al.</i> , "Autoactivation of Type-1 Parathyroid Hormone Receptors Containing a Tethered Ligand," <i>J. Biol. Chem.</i> 275:19456-19460, The American Society for Biochemistry and Molecular Biology, Inc. (2000)			
/AG/	NPL30	Shimizu, M., <i>et al.</i> , "Minimization of Parathyroid Hormone," <i>J. Biol. Chem.</i> 275:21836-21834, The American Society for Biochemistry and Molecular Biology, Inc. (2000)			
/AG/	NPL31	Shimizu, M., <i>et al.</i> , "Enhanced Activity in Parathyroid Hormone-(1-14) and -(1-11): Novel Peptides for Probing Ligand-Receptor Interactions," <i>Endocrinol.</i> 142:3068-3074, Endocrine Society (2001)			
/AG/	NPL32	Shimizu, N., <i>et al.</i> , "Parathyroid Hormone (PTH)-(1-14) and -(1-11) Analogs Conformationally Constrained by α -Aminosobutyric Acid Mediate Full Agonist Responses via the Juxtamembrane Region of the PTH-1 Receptor," <i>J. Biol. Chem.</i> 276:49003-49012, The American Society for Biochemistry and Molecular Biology, Inc. (2001)			
/AG/	NPL33	Slovik, D.M., <i>et al.</i> , "Restoration of Spinal Bone in Osteoporotic Men by Treatment with Human Parathyroid Hormone (1-34) and 1,25-Dihydroxyvitamin D," <i>J. Bone Min. Res.</i> 1:377-381, Mary Ann Liebert, Inc. (1986)			
/AG/	NPL34	Takasu, H., <i>et al.</i> , "Amino Terminal Modifications of Human Parathyroid Hormone (PTH) Selectively Alter Phospholipase C Signaling via The Type 1 PTH Receptor: Implications of Design of Signal-Specific PTH Ligands," <i>Biochemistry</i> 38:13453-13460, American Chemical Society (1999)			
/AG/	NPL35	Tregear, G.W., <i>et al.</i> , "Bovine Parathyroid Hormone: Minimum Chain Length of Synthetic Peptide Required for Biological Activity," <i>Endocrinol.</i> 93:1349-1353, The Endocrine Society (1973)			
/AG/	NPL36	Wold, F., "Posttranslational Protein Modifications: Perspectives and Prospects," in <i>Posttranslational Covalent Modifications of Proteins</i> , B.C. Johnson, eds., Academic Press, Inc., New York, pp. 1-12 (1983)			

Examiner Signature	/Anish Gupta/	Date Considered	02/01/2009
--------------------	---------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.